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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,202	11/12/2003	Randall J. Huebner	ACM 352	8269

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EXAMINER	
DUFOUR, DEVANIE A	

ART UNIT	PAPER NUMBER
3733	

MAIL DATE	DELIVERY MODE
09/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/712,202	HUEBNER ET AL.	
	Examiner	Art Unit	
	DEVANIE DUFOUR	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-9,11,13-15,17-26,28 and 31-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-9,11,13-15,17-26,28 and 31-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-9, 13-15, 19, 21-22, 24-26, 28, 31-37, 39-41 rejected under 35 U.S.C. 102(b) as being anticipated by Hamman (U.S. Pat. No. 6,187,008 B1 as cited by applicant).

Hamman discloses a method of compressing a bone (abstract), comprising: selecting a bone screw (Fig. 1) including a shank (12 and a portion of 14) including a thread (18) disposed externally for threaded engagement with bone, the shank defining a long axis (axis of bone screw) and a direction of advancement into bone (Fig. 1), and a head (distal portion near 16 including barbs 34) connected to the shank (as shown) and defining three or more shoulders (3 barbs 34 as shown) disposed at spaced positions generally along the head, each shoulder facing generally toward the direction of advancement (when petals 32 are flexed outward, barbs will have a surface that faces the direction of advancement) and extending partially or completely around the head (barbs 34 extend partially around head) to define a respective plane disposed orthogonally to the long axis (barbs 34 orthogonal to the long axis); and installing the bone screw as a unit in a bone (column 2, lines 18-20, lines 44-53) such that a portion of the bone near the head is engaged by two or more of the shoulders (Fig. 1) and is urged toward a portion of the bone near the shank (Fig. 1, column 2, lines 44-53).

The step of selecting a bone screw includes a step of selecting a bone screw in which the shank (Fig. 1, 12 and a portion of 14) has a proximal portion adjacent the head (portion of 14) and a distal portion spaced from the head (12), and wherein the proximal portion has at least substantially no external thread formed externally on the bone screw (portion of 14 has no external threads). The step of selecting a bone screw includes a step of selecting a bone screw that is self-tapping (Fig. 1, self tapping flutes 22, column 2, lines 9-12). The step of selecting a bone screw includes a step of selecting a bone screw in which the shank includes a tip region (Fig. 1, 12) configured to cut a hole in the bone as the bone screw is advanced into the bone (Fig. 1, self tapping flutes 22 in tip region 12, column 2, lines 9-12). The step of selecting a bone screw includes a step of selecting a bone screw in which the shoulders are formed/defined by a plurality of ridges, a plurality of grooves, or both (Fig. 1, shoulders are barbs 34 which are ridges). The step of selecting a bone screw includes a step of selecting a bone screw in which the plurality of shoulders have a corresponding plurality of diameters, and wherein the diameters decrease successively toward the shank (Fig. 3, The wedge 38 will expand petals 32 causing head to flex outward in a conical shape. Once expanded, the barbs will have a plurality of diameters which decrease successively toward the shank 12). The step of selecting a bone screw includes a step of selecting a bone screw in which the head is shaped generally as a frustum of a cone/generally frustoconical in shape. (Fig. 3, the wedge 38 will expand petals 32 causing head to flex outward in a conical shape). The step of selecting a bone screw includes a step of selecting a bone screw in which the head includes at least three steps defined by stepwise decreases in the diameter of the head, and wherein the plurality of shoulders are included in the plurality of steps (Fig. 3, the wedge 38 will expand petals 32 causing head to flex outward in a

conical shape. Once expanded, the three barbs/steps/shoulders will have a plurality of diameters which stepwise decrease). The step of selecting a bone screw includes a step of selecting a bone screw in which the head and the shank each are part of a same monolithic structure (Applicant's originally filed application does not detail a monolithic structure. Applicant discloses, on page 9, lines 15-21, the head and the shank may be formed unitarily as a single piece. Hamman discloses the implant can be a unitary piece made of a single material or piece, column 1, lines 67 column 2, line 1, which is equivalent).

Hamman discloses a method of compressing a bone (abstract), comprising: selecting a bone screw (Fig. 1) including a shank (12 and a portion of 14) including a proximal region (portion of 14), a distal region (12), and a thread disposed externally for threaded engagement with bone and restricted to the distal region (threads only on 12), the proximal region having at least substantially no thread formed externally on the bone screw (portion of 14 having no threads), and a head (distal portion near 16 including barbs 34) connected to the shank adjacent the proximal region (distal portion 16 including barbs 34 connected to shank adjacent to portion of 14) and defining a plurality of spaced shoulders (3 barbs 34) disposed generally along the head (as shown), each shoulder extending in a respective plane to describe at least an arc of a circle (barbs 34 extend partially around head creating an arc of a circle); and installing the bone screw as a unit in a bone (column 2, lines 18-20, lines 44-53) such that a portion of the bone near the head is engaged by two or more of the shoulders (Fig. 1) and is urged toward a portion of the bone near the shank (Fig. 1, column 2, lines 44-53).

The step of selecting a bone screw includes a step of selecting a bone screw in which the shank defines a long axis (Fig. 3, longitudinal axis of shank), wherein the head has a maximum

diameter (maximum diameter near 16 when wedge 38 is seated), wherein the head has an axial length that is measured parallel to the long axis (length of head portion measure longitudinally, including portion with barbs 34 and an upper portion of 14), wherein the head has an aspect ratio defined by the axial length of the head relative to the maximum diameter of the head, and wherein the aspect ratio is at least 1:1 (The length is variable such that a portion of the shaft 14 can be included in the length of the head. There exists at least one length of the head such that the aspect ratio is at least 1:1). The step of selecting a bone screw selects a bone screw in which the head and the shank each are part of a same monolithic structure (Applicant's originally filed application does not detail a monolithic structure. Applicant discloses, on page 9, lines 15-21, the head and the shank may be formed unitarily as a single piece. Hamman discloses the implant can be a unitary piece made of a single material or piece (column 1, lines 67 column 2, line 1) which is equivalent).

Hamman discloses a method of compressing a bone with a bone screw, comprising: forming a hole in the bone (column 2, lines 44-45); selecting a bone screw (Fig. 1) having a shank (12 and portion of 14) and a head (distal portion near 16 including barbs 34) connected to the shank (as shown), the head and the shank each being part of a same monolithic structure (Applicant's originally filed application does not detail a monolithic structure. Applicant discloses, on page 9, lines 15-21, the head and the shank may be formed unitarily as a single piece. Hamman discloses the implant can be a unitary piece made of a single material or piece, column 1, lines 67 column 2, line 1, which is equivalent), the head defining at least three (3 barbs 34) disposed at spaced positions generally along the head (as shown), each shoulder facing generally toward the direction of advancement (when petals 32 are flexed outward, barbs will

have one surface that faces the direction of advancement) and extending partially or completely around the head (barbs 34 extend partially around head) to define a respective plane disposed orthogonally to the long axis (barbs 34 orthogonal to the long axis); and advancing first the shank and then the head of the bone screw into the hole (Fig. 1, column 2, lines 46-47) via threaded engagement of the shank with the bone (Fig. 1, column 2, lines 9-12 and lines 46-47) such that a portion of the bone near the head is engaged by two or more of the shoulders (Fig. 1, column 2, lines 47-53) and is urged toward a portion of the bone near the shank (Fig. 1, column 2, lines 44-53).

The step of forming a hole includes a step of forming a bore (holes 48) and a counterbore (counterbore is a larger hole created when petals flex outward biting into surrounding bone, column 2 lines 24-33), and wherein the step of advancing disposes the head and the shank at least substantially in the counterbore (head is in created counterbore) and the bore (shank is in hole 48), respectively (column 2, lines 44-45). The step of forming a hole is performed by the step of advancing (Fig. 1, self-taping flutes of 12, column 2, lines 9-12). The portion of the bone near the head and the portion of the bone near the shank are separated by a fracture in the bone (Fig. 1, column 2, lines 44-58, abstract). The step of selecting a bone screw includes a step of selecting a bone screw in which one or more of the shoulders slope radially outward, generally toward the direction of advancement into bone (Fig. 3, when petals 32 are flexed outward, at least one surface of the barbs will slope toward the direction of advancement).

Hamman discloses a method of compressing a bone (abstract), comprising: selecting a bone screw (Fig. 1) including a shank (12 and a portion of 14) including a thread (18) disposed externally for threaded engagement with bone, the shank defining a long axis (axis of bone

screw) and a direction of advancement into bone (Fig. 1), and a head (distal portion near 16 including barbs 34) connected to the shank (as shown) such that the shank and the head each are part of a same monolithic structure (Applicant's originally filed application does not detail a monolithic structure. Applicant discloses, on page 9, lines 15-21, the head and the shank may be formed unitarily as a single piece. Hamman discloses the implant can be a unitary piece made of a single material or piece, column 1, lines 67 column 2, line 1, which is equivalent), the head including at least three of spaced shoulders (3 barbs 34) of different diameter (Fig. 3, The wedge 38 will expand petals 32 causing head to flex outward in a conical shape. Once expanded, the barbs will have a plurality of diameters which decrease successively toward the shank 12), each shoulder facing generally toward the direction of advancement (when petals 32 are flexed outward, at least one surface of the barbs will face the direction of advancement) and extending partially or completely around the long axis in a respective path defining a plane (each barb extend partially around long axis and each barb is in a single plane); and installing the bone screw as a unit in a bone (column 2, lines 18-20, lines 44-53) such that a portion of the bone near the head is engaged by two or more of the shoulders (Fig. 1) and is urged toward a portion of the bone near the shank (Fig. 1, column 2, lines 44-53).

The step of selecting a bone screw includes a step of selecting a bone screw in which each shoulder follows a respective path defining a plane oriented orthogonally to the long axis (each barb 34 defines a plane orientated orthogonal to the long axis, Fig. 1). The step of selecting a bone screw includes a step of selecting a bone screw in which each shoulder follows a respective path corresponding to at least an arc of a circle (each barb 34 is an arc of a circle, Fig. 1). The step of selecting a bone screw includes a step of selecting a bone screw in which each

shoulder slopes radially outward, generally toward the direction of advancement into bone (Fig. 3, when petals 32 are flexed outward, at least one surface of the barbs will face in the direction of advancement). The step of selecting a bone screw includes a step of selecting a bone screw in which the head includes at least one generally cylindrical segment disposed at least partially between a pair of the shoulders (Fig. 1, cylindrical region of head between barbs 34).

Claims 5, 11, 17, 18, 20, 21, 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Tronzo (U.S. Pat. No. 4,940,467 as previously cited).

Tronzo discloses a method of compressing a bone, comprising: selecting a bone screw (Fig. 1) including a shank (30) including a thread disposed externally for threaded engagement with bone (34), the shank defining a long axis (longitudinal axis of bone screw) and a direction of advancement into bone (Fig. 10), and a head connected to the shank (11) and defining three or more shoulders (3 locking rings 24) disposed at spaced positions generally along the head, each shoulder facing generally toward the direction of advancement (each shoulder has a surface that faces toward the direction of advancement) and extending partially or completely around the head (shoulders extend completely around the head) to define a respective plane disposed orthogonally to the long axis (at least one surface of shoulder is orthogonal); and installing the bone screw as a unit in a bone such that a portion of the bone near the head is engaged by two or more of the shoulders and is urged toward a portion of the bone near the shank (bone screw assembly 10 is inserted into each hole, locking rings 24 prevent backing out, Fig. 10, column 6 lines 32-50).

The step of selecting a bone screw includes a step of selecting a bone screw in which one or more of the plurality of shoulders extend in a closed loop corresponding to a circle (Fig. 1, locking rings 24 are a closed loop). The step of selecting a bone screw includes a step of selecting a bone screw in which the shank and the head define opposing ends of the bone screw and further define an axial bore extending between the opposing ends (both 11 and 30 are cannulated for insertion over a guide pin, column 3, lines 20-26). The step of selecting a bone screw includes a step of selecting a bone screw in which the axial bore (Fig. 1, 11 and 30 are cannulated for insertion over a guide pin, column 3, lines 20-26) includes a widened region (hex shaped recess 18 is larger than axial bore due to 30 fitting inside 11) configured to receive a tool that engages the head (column 4, lines 61-66). The step of selecting a bone screw includes a step of selecting a bone screw in which the head is rotatably and/or slidably connected to the shank (Fig. 1, 11 and 30 slidably connected, column 5, lines 26-32).

Tronzo discloses a method of compressing a bone, comprising: selecting a bone screw (Fig. 1) including a shank (30) including a proximal region (region closest to 11 without threads), a distal region (32), and a thread disposed externally (34) for threaded engagement with bone and restricted to the distal region (as shown, threads 34 only on distal region 32), the proximal region having at least substantially no thread formed externally on the bone screw (as shown, proximal region closest to 11 without threads), and a head (11) connected to the shank adjacent the proximal region (11 connected to 30 adjacent to region of 30 without threads) defining a plurality of spaced shoulders (3 locking rings 24) disposed generally along the head, each shoulder extending in a respective plane to describe at least an arc of a circle (each locking ring extends in a single plane and describes complete circles); and installing the bone screw as a

unit in a bone such that a portion of the bone near the head is engaged by two or more of the shoulders and is urged toward a portion of the bone near the shank (bone screw assembly 10 is inserted into each hole, locking rings 24 prevent backing out, Fig. 10, column 6 lines 32-50).

The step of selecting a bone screw includes a step of selecting a bone screw in which the shoulders describe complete circles (Fig. 1, locking rings 24 describes complete circles).

Claims 35 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Carchidi et al. (U.S. Pat. No. 5,971,985 as previously cited).

Carchidi et al. (Fig. 1) discloses a method of compressing a bone, comprising: selecting a bone screw including a shank (12f) including a thread disposed externally for threaded engagement with bone, the shank defining a long axis (longitudinal axis of screw) and a direction of advancement into bone (Fig. 1), and a head (proximal portion including 3 shoulders, see attached drawing) connected to the shank such that the shank and the head each are part of a same monolithic structure (shank and head formed from continuous structure), the head including at least three a plurality of spaced shoulders of different diameter (see attached drawing), each shoulder facing generally toward the direction of advancement (at least one surface on shoulders are toward direction of insertion) and extending partially or completely around the long axis in a respective path defining a plane (shoulders extend completely around long axis); and installing the bone screw in a bone (threads begin to engage the bone defining the bore, column 3 lines 39-43) such that a portion of the bone near the head is engaged by two or more of the shoulders and is urged toward a portion of the bone near the shank (dome shaped driving head, first shoulder, retain tissue graft which is a portion of bone near the head, the

underside of dome driving head has a reduced diameter for seating the graft material such that the two distal shoulder engage the graft and urges the graft toward the shank, column 2, lines 52-65,).

The step of selecting a bone screw includes a step of selecting a bone screw in which each shoulder extends completely around the long axis in a closed loop (shoulders extend completely around long axis).

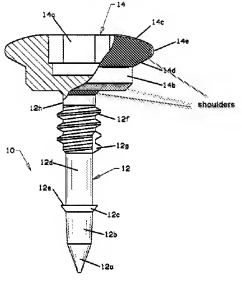

FIG 1

Response to Arguments

Applicant's arguments with respect to claims 5, 6, 19, 21, 24, 25, 28, 35, and 39 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See form 892.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEVANIE DUFOUR whose telephone number is (571)270-7843. The examiner can normally be reached on Mon-Thurs 7:00 a.m.-5:00 p.m., EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733